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Abstract

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Grant Number: 7R01NR005084-02
PI Name: SCHWARTZ, ANNA L.
PI Title:
Project Title: BREAST CANCER SURVIVORS: EXERCISE AND RALOXIFENE

Abstract: *It is estimated that 178,799 women will be diagnosed with breast cancer in 1998. While breast cancer has become more treatable, the long-term treatment-related side effects have a significant negative effect on morbidity and non-cancer related risk of mortality. The increasingly common use of adjuvant chemotherapy for breast cancer has led to a rise in long-term treatment- related side effects including osteoporosis, early menopause, increased risk for cardiovascular disease, and declines in quality of life. Osteoporosis is a major public health problem and a common finding in breast cancer survivors. Nationally, 20 million women are estimated to be at risk for osteoporosis, with 1.3 million sustaining osteoporotic fractures. Four factors place breast cancer survivors at high risk for muscle, bone and cardiovascular complications: inactivity, menopause (especially premature menopause), chemotherapy and catabolic steroids. This innovative study will use a randomized placebo-controlled design to test the effects of (a) exercise and (b) raloxifene in postmenopausal breast cancer survivors (N=240) between 3 months and one year after completing chemotherapy on: one resorption, formation and density (serum osteocalcin and bone specific AST, urine n-telopeptide, DEXA scan); multidimensional quality of life (SF-36, 12-minute walk, muscle strength, fatigue, menopausal vasomotor symptoms positive and negative affect, and Trail Making); and lipid profile (serum lipid levels). Subjects in the exercise intervention will follow a supervised home-based exercise program and asked to exercise 5 days/week. Exercise dose and adherence will be monitored with Caltrac accelerometers, exercise logs, regularly scheduled follow-up phone calls and supervised exercise sessions, and results on 12-minute walks and 1-repetition maximum tests. Subjects in the ralosifene and placebo control groups will be asked to take the medication (60mg/day) or placebo as prescribed. Subjects in the*

exercise+raloxifene group will be asked to take the medication and follow the exercise program. All subjects will be instructed to take a daily calcium supplement (1000mg/day). Subjects will be followed for 2 years. All measures will be re-evaluated at 3- month intervals except the DEXA scans, which will be obtained at 12-month intervals. Results of this study may reduce the morbidity, mortality and health care costs of these common, long-term complications that confront breast cancer survivors.

Thesaurus Terms:
breast neoplasm, chemoprevention, drug adverse effect, exercise, human therapy evaluation, physiologic bone resorption, raloxifene, remission /regression, tamoxifen bone density, dietary calcium, long term survivor, osteoporosis, outcomes research, quality of life
clinical research, female, human subject, photon absorptiometry

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